

CLAIMS:

1. A catheter assembly comprising:

a catheter, the catheter comprising a catheter shaft, the catheter shaft defining a first guide wire lumen for passage of a first guide wire therethrough;

5 a rotatable sheath, the rotatable sheath being disposed about at least a portion of the catheter shaft and rotatable thereabout, the rotatable sheath having a length substantially less than that of the catheter shaft; and

a secondary guide wire housing, the secondary guide wire housing defining a secondary guide wire lumen for passage of a secondary guide wire therethrough, at least a 10 first distal portion of the guide wire housing being engaged to at least a first proximal portion of the rotatable sheath.

2. The assembly of claim 1 further comprising a stent, the stent being expandable from a reduced stent state to an expanded stent state, and defining a flow path between a proximal end opening and a distal end opening, the stent being at least partially constructed 15 from a plurality of interconnected stent members that define a plurality of cell openings therebetween, each of the cell openings being in fluid communication with the flow path, in the reduced stent state the stent is disposed about at least a portion of the rotatable sheath and at least a portion of the secondary guide wire housing, a distal end portion of the secondary guide wire housing exiting the flow path of the stent through one of the plurality 20 of cell openings.

3. The assembly of claim 2 wherein the stent is selected from at least one member of the group consisting of: a self-expanding stent, a balloon-expandable stent, a hybrid expandable stent and any combination thereof.

4. The assembly of claim 1 wherein the catheter shaft further comprises a medical 25 balloon fixedly mounted thereto, the medical balloon expandable from a reduced configuration to an expanded configuration, the catheter shaft further defining an inflation lumen, the inflation lumen being in fluid communication with the medical balloon.

5. The assembly of claim 4, wherein the rotatable sheath is rotatably disposed about at least a portion of the medical balloon.

6. The assembly of claim 2 wherein at least a portion of the stent is coated with at least one therapeutic agent.
7. The assembly of claim 6 wherein the at least one therapeutic agent is at least one non-genetic therapeutic agent selected from at least one member of the group consisting of:
 - 5 anti-thrombogenic agents such as heparin, heparin derivatives, urokinase, and PPack (dextrophenylalanine proline arginine chloromethylketone); anti-proliferative agents such as enoxaprin, angiopeptin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid; anti-inflammatory agents such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine; antineoplastic/antiproliferative/anti-miotic agents such as paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors; anesthetic agents such as lidocaine, bupivacaine and ropivacaine; anti-coagulants such as D-Phe-Pro-Arg chloromethyl keton, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet peptides; vascular cell growth promoters such as growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, and translational promoters, vascular cell growth inhibitors such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors,
 - 10 replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin; bifunctional molecules consisting of an antibody and a cytotoxin; cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogenous vascoactive mechanisms, and any combinations thereof.
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- 25 8. The assembly of claim 6 wherein the at least one therapeutic agent is at least one genetic therapeutic agent selected from at least one member of the group consisting of: anti-sense DNA and RNA; DNA coding for anti-sense RNA, tRNA or rRNA to replace defective or deficient endogenous molecules; angiogenic factors including growth factors such as acidic and basic fibroblast growth factors, vascular endothelial growth factor, epidermal growth factor, transforming growth factor α and β , platelet-derived endothelial

growth factor, platelet-derived growth factor, tumor necrosis factor α , hepatocyte growth factor and insulin like growth factor; cell cycle inhibitors including CD inhibitors, thymidine kinase ("TK") and other agents useful for interfering with cell proliferation; at least one of the family of bone morphogenic proteins ("BMP's") such as BMP-2, BMP-3, 5 BMP-4, BMP-5, BMP-6 (Vgr-1), BMP-7 (OP-1), BMP-8, BMP-9, BMP-10, BMP-11, BMP-12, BMP-13, BMP-14, BMP-15, and BMP-16. Any of BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 and BMP-7; dimeric proteins such as homodimers, heterodimers, or combinations thereof, alone or together with other molecules; molecules capable of inducing an upstream or downstream effect of a BMP such as "hedgehog" proteins, or the 10 DNA's encoding them and any combinations thereof.

9. The assembly of claim 6 wherein the at least one therapeutic agent is at least one type of cellular material selected from at least one member of the group consisting of: cells of human origin (autologous or allogeneic); cells of non-human origin (xenogeneic) and any combination thereof.

15 10. The assembly of claim 6 wherein the cellular material is selected from at least one member of the group consisting of: side population cells; lineage negative cells; lineage negative CD34 $^{-}$ cells; lineage negative CD34 $^{+}$ cells; lineage negative cKit $^{+}$ cells; mesenchymal stem cells; cord blood cells; cardiac or other tissue derived stem cells; whole bone marrow; bone marrow mononuclear cells; endothelial progenitor cells; satellite cells; 20 muscle derived cells; go cells; endothelial cells; adult cardiomyocytes; fibroblasts; smooth muscle cells; cultures of mesenchymal stem cells with 5-aza forces differentiation into cardiomyocytes; adult cardiac fibroblasts + 5-aza; genetically modified cells; tissue engineered grafts; MyoD scar fibroblasts; Pacing cells; embryonic stem cell clones; embryonic stem cells; fetal or neonatal cells; immunologically masked cells; tissue 25 engineered grafts; genetically modified cells; teratoma derived cells and any combinations thereof.

30 11. The assembly of claim 6 wherein the at least one therapeutic agent comprises at least one polymer coating, the at least one coating selected from at least one member of the group consisting of: polycarboxylic acids; cellulosic polymers, including cellulose acetate and cellulose nitrate; gelatin; polyvinylpyrrolidone; cross-linked polyvinylpyrrolidone;

polyanhydrides including maleic anhydride polymers; polyamides; polyvinyl alcohols; copolymers of vinyl monomers such as EVA; polyvinyl ethers; polyvinyl aromatics; polyethylene oxides; glycosaminoglycans; polysaccharides; polyesters including polyethylene terephthalate; polyacrylamides; polyethers; polyether sulfone; polycarbonate;

5 polyalkylenes including polypropylene, polyethylene and high molecular weight polyethylene; halogenated polyalkylenes including polytetrafluoroethylene; polyurethanes; polyorthoesters; proteins; polypeptides; silicones; siloxane polymers; polylactic acid; polyglycolic acid; polycaprolactone; polyhydroxybutyrate valerate and blends and copolymers thereof; coatings from polymer dispersions such as polyurethane dispersions

10 (BAYHDROL®, etc.), fibrin, collagen and derivatives thereof; polysaccharides such as celluloses, starches, dextrans, alginates and derivatives; hyaluronic acid; squalene emulsions; polyacrylic acid, a copolymer of polylactic acid and polycaprolactone; medical-grade biodegradable materials such as PGA-TMC, Tyrosine-Derived Polycarbonates and arylates; polycaprolactone co butyl acrylate and other co polymers; Poly-L-lactic acid

15 blends with DL-Lactic Acid; Poly(lactic acid-co-glycolic acid); polycaprolactone co PLA; polycaprolactone co butyl acrylate and other copolymers; Tyrosine-Derived Polycarbonates and arylate; poly amino acid; polyphosphazenes; polyiminocarbonates; polydimethyltrimethylcarbonates; biodegradable CA/PO₄'s; cyanoacrylate; 50/50 DLPLG; polydioxanone; polypropylene fumarate; polydepsipeptides; macromolecules such as

20 chitosan and Hydroxylpropylmethylcellulose; surface erodible material; maleic anhydride copolymers; zinc-calcium phosphate; amorphous polyanhydrides; sugar; carbohydrate; gelatin; biodegradable polymers; and polymers dissolvable in bodily fluids; A block copolymers; B block copolymers and any combinations thereof.

12. The assembly of claim 5 further comprising a lubricious coating, the lubricious

25 coating positioned between at least a portion of the rotatable sheath and at least a portion of the medical balloon.

13. The assembly of claim 5 further comprising a rotatable collar, the rotatable collar rotatably disposed about a portion of the catheter shaft proximal of the medical balloon, at least a first proximal portion of the secondary guide wire housing being engaged to at least

30 a portion of the rotatable collar.

14. The assembly of claim 13 wherein the rotatable collar defines a catheter shaft lumen therethrough, the catheter shaft being positioned within the catheter shaft lumen, the catheter shaft lumen having a diameter greater than an outer diameter of the catheter shaft.
15. The assembly of claim 1 wherein the secondary guide wire housing comprises an external tubular member and an internal tubular member, the internal tubular member defining the secondary guide wire lumen.
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16. The assembly of claim 15 wherein the external tubular member is a spiral cut hypotube.
17. The assembly of claim 15 wherein the external tubular member is at least partially constructed of metal, the external tubular member defining at least one opening therethrough.
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18. The assembly of claim 15 wherein the internal tubular member is a flexible polymer material.
19. The assembly of claim 1 wherein the rotatable sheath is at least partially constructed from a hydrophilic polymer material.
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20. The assembly of claim 1 wherein the rotatable sheath is at least partially constructed from a tecophilic material.
21. The assembly of claim 1 wherein the rotatable sheath is at least partially constructed from a first material and a second material.
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22. The assembly of claim 21 wherein the rotatable sheath is at least partially constructed from at least one material of the group consisting of: hydrophilic polyurethanes, aromatic polyurethanes, polycarbonate base aliphatic polyurethanes, engineering polyurethane, elastomeric polyamides, block polyamide/ethers, polyether block amide, silicones, polyether-ester, polyester, polyester elastomer, polyethylene, polyamide, high-density polyethylene, polyetheretherketone, polyimide, polyetherimide, liquid crystal polymers, acetal, and any combination thereof.
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23. The assembly of claim 21 wherein the first material is a polymer matrix and the second material is at least one distinct member of reinforcing material at least partially supported within the polymer matrix.

24. The assembly of claim 23 wherein polymer matrix is selected from at least one material from the group consisting of: hydrophilic polyurethanes, aromatic polyurethanes, polycarbonate base aliphatic polyurethanes, engineering polyurethane, elastomeric polyamides, block polyamide/ethers, polyether block amide, silicones, polyether-ester, polyester, polyester elastomer, polyethylene and any combination thereof.
- 5 25. The assembly of claim 23 wherein the reinforcing material is selected from at least one material of the group consisting of polyamide, polyethylene, high-density polyethylene, polyetheretherketone, polyimide, polyetherimide, liquid crystal polymers, acetal, and any combination thereof.
- 10 26. The assembly of claim 13 further comprising at least one lock member, the at least one lock member fixedly engaged to the catheter shaft at a position adjacent to the rotatable collar, the at least one lock member having an outer diameter greater than the diameter of the catheter shaft lumen defined by the rotatable collar.
- 15 27. The assembly of claim 26 wherein the at least one lock member comprises a proximal lock member and a distal lock member, the proximal lock member being fixedly engaged to the catheter shaft at a position proximal to the rotatable collar and the distal lock member being fixedly engaged to the catheter shaft at a position distal to the rotatable collar.
- 20 28. The assembly of claim 26 wherein the at least one lock member defines a catheter engagement chamber, and wherein the at least one lock member is movable from an unengaged position to an engaged position, in the engaged position the catheter shaft extends longitudinally through catheter shaft engagement chamber and the at least one lock member is disposed about the catheter shaft and is frictionally and fixedly engaged thereto.
- 25 29. The assembly of claim 28 wherein the at least one lock member comprises a first portion and a second portion, a first end of the first portion and a first end of the second portion being pivotally engaged one to the other.
30. The assembly of claim 29 wherein a second end of the first portion comprises a locking tab and the second end of the second portion comprises a receiving region, in the engaged position the locking tab is lockingly engaged within the receiving region.

31. The assembly of claim 5 wherein the medical balloon comprises a proximal cone region, a distal cone region and a body region extending therebetween, the rotatable sleeve being rotatably disposed about at least a portion of the body region, the assembly further comprising a proximal balloon cone retaining member and a distal balloon cone retaining, 5 the proximal balloon cone retaining member being at least partially disposed about the proximal cone region of the medical balloon in the reduced configuration, and the distal balloon cone retaining member being at least partially disposed about the distal cone region of the medical balloon in the reduced configuration.
32. The assembly of claim 31 wherein in the expanded configuration the proximal 10 balloon cone retaining member is retracted off of the proximal cone region and the distal balloon cone retaining member is retracted off of the distal cone region.
33. The assembly of claim 31 wherein the proximal balloon cone retaining member and the distal balloon cone retaining member are a single member.
34. The assembly of claim 33 wherein at least a portion of the single member defines a 15 longitudinal opening through which at least the proximal cone region of the balloon is removably received therethrough.
35. The assembly of claim 31 wherein at least a portion of at least one of the proximal balloon cone retaining member and the distal balloon cone retaining member comprises a rotatable sheath engagement member, the rotatable sheath engagement member being a 20 portion of the at least one of the proximal balloon cone retaining member and the distal balloon cone retaining member having an outer diameter sufficient to frictionally engage the rotatable sheath when the rotatable sheath is in the reduced state and the medical balloon is in the reduced configuration.